

AMENDED IN ASSEMBLY JANUARY 4, 2016

CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

ASSEMBLY BILL

No. 463

Introduced by Assembly Member Chiu

February 23, 2015

An act to add Chapter 9 (commencing with Section 127675) to Part 2 of Division 107 of the Health and Safety Code, relating to pharmaceuticals.

LEGISLATIVE COUNSEL'S DIGEST

AB 463, as amended, Chiu. Pharmaceutical Cost Transparency Act of ~~2015~~. 2016.

Existing law establishes the Office of Statewide Health Planning and Development, which is vested with all the duties, powers, responsibilities, and jurisdiction of the State Department of Public Health relating to health planning and research development.

This bill would require each manufacturer of a prescription drug, made available in California, that has a wholesale acquisition cost of \$10,000 or more annually or per course of treatment to file a report, no later than May 1 of each year, with the Office of Statewide Health Planning and Development on the costs for each qualifying drug, as specified. The bill would require the office to issue a report annually to the Legislature outlining the information submitted pursuant to ~~this act, and the office would be required~~ *the bill and* to post the report on its Internet Web site. The bill would also require the office to convene an advisory workgroup, as provided, to develop the reporting form required by ~~this act. bill. The bill would require the office to maintain the confidentiality of any information submitted by a prescription drug~~

manufacturer pursuant to those provisions that the director of the office deems to be confidential and proprietary.

Existing constitutional provisions require that a statute that limits the right of access to the meetings of public bodies or the writings of public officials and agencies be adopted with findings demonstrating the interest protected by the limitation and the need for protecting that interest.

This bill would make legislative findings to that effect.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: no.

The people of the State of California do enact as follows:

1 SECTION 1. Chapter 9 (commencing with Section 127675)
2 is added to Part 2 of Division 107 of the Health and Safety Code,
3 to read:

4
5 CHAPTER 9. PHARMACEUTICAL COST TRANSPARENCY ACT OF
6 ~~2015~~ 2016
7

8 127675. The Legislature finds and declares all of the following:

9 (a) It is the intent of the Legislature to make information
10 available to the public about the cost of ultra-high-priced
11 pharmaceuticals, in order to make pharmaceutical pricing as
12 transparent as the pricing in other sectors of the health care
13 industry.

14 (b) To fulfill this goal, the Legislature finds that there should
15 be annual cost reporting on the most expensive drugs that would
16 be of use by policymakers, government agencies, and others to
17 understand costs for these important products.

18 127676. (a) Each manufacturer of a prescription drug, made
19 available in California, that has a wholesale acquisition cost (WAC)
20 of ten thousand dollars (\$10,000) or more annually or per course
21 of treatment, shall file a report pursuant to this section on the costs
22 for each qualifying drug.

23 (b) The report shall include all of the following for each drug:

24 (1) The total costs for the production of the drug, including all
25 of the following:

1 (A) The total research and development costs paid by the
2 manufacturer, and separately, the total research and development
3 costs paid by any predecessor in the development of the drug.

4 (B) The total costs of clinical trials and other regulatory costs
5 paid by the manufacturer, and separately, the total costs of clinical
6 trials and other regulatory costs paid by any predecessor in the
7 development of the drug.

8 (C) The total costs for materials, manufacturing, and
9 administration attributable to the drug.

10 (D) The total costs paid by any entity other than the
11 manufacturer or predecessor for research and development,
12 including any amount from federal, state, or other governmental
13 programs or any form of subsidies, grants, or other support.

14 (E) Any other costs to acquire the drug, including costs for the
15 purchase of patents, ~~licensing~~ *licensing*, or acquisition of any
16 corporate entity owning any rights to the drug while in
17 development, or all of these.

18 ~~(F)~~

19 (2) The total marketing and advertising costs for the promotion
20 of the drug directly to consumers, including, but not limited to,
21 costs associated with ~~direct to consumer~~ *direct-to-consumer*
22 coupons and amount redeemed, total marketing and advertising
23 costs for promotion of the drug directly or indirectly to prescribers,
24 and any other advertising for the drug.

25 ~~(2)~~

26 (3) A cumulative annual history of average wholesale price
27 (AWP) and WAC increases for the drug (expressed as percentages),
28 including the months each increase in each category, AWP and
29 WAC, took effect.

30 ~~(3)~~

31 (4) The total profit attributable to the drug as represented in
32 total dollars and represented as a percentage of the total company
33 profits that were derived from the sale of the drug.

34 ~~(4)~~

35 (5) The total amount of financial assistance the manufacturer
36 has provided through patient prescription assistance programs, if
37 available.

38 (6) *The total costs of drugs or research projects that failed to*
39 *succeed through the process to market approval.*

1 (c) (1) All of the information in subdivision (b) shall be
2 itemized and documented by the manufacturer, and audited by a
3 fully independent third-party auditor prior to filing.

4 (2) *The information reported by a manufacturer pursuant to*
5 *paragraph (1) of subdivision (b) shall be limited to the time period*
6 *from five years prior to the filing date of an Investigational New*
7 *Drug application with the United States Food and Drug*
8 *Administration to the approval date of the New Drug Application*
9 *by the United States Food and Drug Administration. This*
10 *paragraph shall not prohibit a manufacturer from separately*
11 *providing that information outside of that time period.*

12 (d) The information required by this section shall be filed
13 annually with the ~~Office of Statewide Health Planning and~~
14 ~~Development~~ office on a form prescribed by the office and shall
15 be submitted no later than May 1 of each year.

16 (e) (1) Notwithstanding Section 10231.5 of the Government
17 Code, the ~~Office of Statewide Health Planning and Development~~
18 office shall issue a report annually to the Legislature outlining the
19 information submitted pursuant to this section, and the office shall
20 post the report publicly on its Internet Web site.

21 (2) A report submitted to the Legislature pursuant to this
22 subdivision shall be submitted in compliance with Section 9795
23 of the Government Code.

24 (f) ~~The Office of Statewide Health Planning and Development~~
25 office shall convene an advisory workgroup to develop the form
26 required by this section. The workgroup shall include, but is not
27 limited to, representatives from the pharmaceutical industry, health
28 care service plans and insurers, pharmacy benefit managers,
29 governmental agencies, consumer advocates, and physicians.

30 (g) *The office shall maintain the confidentiality of any*
31 *information submitted pursuant to this section that the director*
32 *deems to be confidential, proprietary information of the*
33 *prescription drug manufacturer, the disclosure of which would*
34 *cause the manufacturer competitive harm. This confidential*
35 *proprietary information shall not be made public by the office and*
36 *is exempt from disclosure under the California Public Records*
37 *Act (Chapter 3.5 (commencing with Section 6250) of Division 7*
38 *of Title 1 of the Government Code). This paragraph shall not limit*
39 *the disclosure of information that is not attributed to a specific*
40 *manufacturer or that is released in aggregate.*

1 *SEC. 2. The Legislature finds and declares that Section 1 of*
2 *this act, which adds Section 127676 to the Health and Safety Code,*
3 *imposes a limitation on the public's right of access to the meetings*
4 *of public bodies or the writings of public officials and agencies*
5 *within the meaning of Section 3 of Article I of the California*
6 *Constitution. Pursuant to that constitutional provision, the*
7 *Legislature makes the following findings to demonstrate the interest*
8 *protected by this limitation and the need for protecting that*
9 *interest:*

10 *In order to protect proprietary, confidential information from*
11 *prescription drug manufacturers and to protect the integrity of the*
12 *competitive market, it is necessary that this act limit the public's*
13 *right of access to that information.*